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| APPLICATION NO.     | FILING DATE               | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|---------------------|---------------------------|----------------------|--------------------------|------------------|
| 10/666,886          | 09/19/2003                | Andrew H. Segal      | 11111/2003E              | 6806             |
| 29933 75            | 90 02/17/2005             |                      | EXAMINER                 |                  |
| PALMER & DODGE, LLP |                           |                      | LE, EMILY M              |                  |
| KATHLEEN M          | I. WILLIAMS<br>TON AVENUE |                      | ART UNIT                 | PAPER NUMBER     |
| BOSTON, MA 02199    |                           |                      | 1648                     | <del></del>      |
|                     |                           |                      | DATE MAIL ED: 02/12/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | 7   | Application No.          | Applicant(s)                |  |  |  |
|--|---|--------------------------|-----------------------------|--|--|--|
| Office Action Summary  |   | 10/666,886               | SEGAL ET AL.                |  |  |  |
|  |   | Examiner                 | Art Unit                    |  |  |  |
|  |   | Emily Le                 | 1648                        |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |                          |                             |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                          |                             |  |  |  |
| Status   |   |                          |                             |  |  |  |
| 1) Responsive to communication(s) filed on 19 September 2003.  |   |                          |                             |  |  |  |
| 2a) This action is FINAL.  | 2b)⊠ This ad  | ction is non-final.      |                             |  |  |  |
|  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                          |                             |  |  |  |
| Disposition of Claims  |   |                          |                             |  |  |  |
| 4) Claim(s) 1-11 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-11 are subject to restriction and/or election requirement.   |   |                          |                             |  |  |  |
| Application Papers   |   |                          |                             |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |   |                          |                             |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |                          |                             |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                          |                             |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                          |                             |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                          |                             |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                          |                             |  |  |  |
| Added to a market  |   |                          |                             |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |   |                          |                             |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Revi  |   | Paper No(s)/Mail Da      | te                          |  |  |  |
| Information Disclosure Statement(s) (PTO-14 Paper No(s)/Mail Date  |   | 5) Notice of Informal Pa | atent Application (PTO-152) |  |  |  |

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## **DETAILED ACTION**

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## Claims Status

1. Claims 1-11 are pending.

## Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121: in the instant, claims 1-11 are directed to a plurality of distinct vaccine compositions. Applicant is required under 35 U.S.C. 121 to specify a specific vaccine composition for examination. To do so, Applicant is required to specify a specific fusion polypeptide, and a virus or a cell that is included in the vaccine composition. In specifying a specific fusion protein, Applicant must specify a specific ligand (cytokine receptor, CD154--a ligand for CD40, a ligand for adhesion molecule, a ligand for a defensin receptor, a ligand for a heat shock protein, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule, a ligand for an opsonin receptor). If Applicant elects a cytokine receptor, Applicant is required to specify a specific cytokine (GM-CSF, an interleukin, a chemokine, an interferon, a TNF-alpha ligand, a fit-3 ligand). Additionally, if Applicant elects a cell to be included in the claimed vaccine composition, Applicant is required to specify a specific cell (tumor cell, bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, an insect cell).
- 3. The inventions are distinct, each from the other because of the following reasons: All of the above listed entities are patentably distinct from one another. None of the entities share a significant structural similarity among one another. A

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search for one specific vaccine composition is not required for another specific vaccine composition.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday Friday, 8 am 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey S. Parkin, Ph.D. Primary Patent Examiner Art Unit 1648

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